UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ELMER HEISNER, Individually and on Behalf of JAYNE HEISNER,	)	
Plaintiff,	)	**Case No.: 08 C 593**
vs.	)	**Judge Coar**
GENZYME CORPORATION, a Massachusetts Corporation,	)	**Magistrate Judge Denlow**
Defendant.	)	

Defendant Genzyme Corporation's Reply Brief Supporting Its Rule 12 (b)(6) Motion to Dismiss the Complaint

Plaintiff's response offers nothing that would defeat defendant Genzyme Corporation's ("Genzyme") motion to dismiss. With respect to preemption, the plaintiff virtually ignores the impact of *Riegel v. Medtronic*, 128 S. Ct. 999 (2008), which like defendant's product here, involved a Class III device regulated under the Medical Device Amendments to the Food, Drug and Cosmetics Act ("MDA") and given "premarket approval" ("PMA") by the U.S. Food and Drug Administration ("FDA"). For complaints like this one, *Riegel* sweeps broadly, requiring dismissal of the strict liability, negligence and warranty counts. To avoid *Riegel*'s reach, plaintiff would have the court follow *Medtronic v. Lohr*, 518 U.S. 470 (1996), although the decision involves a device regulated under the § 510(k) process (not the PMA process) and, as a result, reached a different conclusion about preemption.

Nor can the plaintiff take refuge in the proposition that his claims "parallel" FDA requirements for Seprafilm. The strict liability, negligence and warranty claims that plaintiff pleads here, under the aegis of state tort laws, would impose requirements that

would vary those mandated by the FDA for Seprafilm's safety and effectiveness. Consequently, such claims are preempted. The count for negligence *per se* does not pass muster, either, for a similar reason: the complaint does not offer a single instance where Genzyme failed to comply with a specific requirement for design, manufacture, marketing, sales or reporting.

Finally, plaintiff offers nothing to support either of his statutory counts. He agrees that Count II, for deceptive practices, should be dismissed. (Response Brief ("Resp. Br.") at 14-15.) Count I, a claim for breach of implied warranty is preempted for the reasons discussed in Genzyme's opening brief ("Open. Br.") at 6-7, and plaintiff has said nothing at all in response to that argument. In short, all of plaintiff's counts suffer from one or more fatal defects. No count can survive the legal bases for Genzyme's motion to dismiss and, therefore, the entire complaint should be dismissed.

ARGUMENT

I. The Court Should Take Judicial Notice of the Undisputed Fact in the Public Record that Seprafilm is a PMA-Approved Class III Medical Device.

Plaintiff's position on judicial notice sidesteps the very fact from the public record that Genzyme offers for consideration. Plaintiff contends that "disputable findings exist concerning the Defendant's compliance with the FDA's Medical Device Amendments (MDA) and Premarket approval process in the manufacturing of their product, Seprafilm, and therefore this Court should not take judicial notice of these findings." (Resp. Br. at 3.) But Genzyme is not asking the Court to take judicial notice of disputed findings about compliance (even assuming that there are such findings).

The undisputed fact in the public record which Genzyme offers is Seprafilm's status as a Class III medical device that was approved by the FDA through the PMA

process. That fact is dispositive of Genzyme's motion because it compels the conclusion that plaintiff's tort claims are preempted and should be dismissed.

Even plaintiff concedes that it is entirely appropriate for the Court, in considering a Rule 12(b)(6) motion to dismiss, to take judicial notice of an undisputed fact in the public record if such a fact establishes that the plaintiff cannot satisfy the 12(b)(6) standard. (Resp. Br. at 3, *citing Gen Elec. Capital Corp. v. Lease Resolution Corp*., 128 F. 3d 1074, 1081 (7th Cir. 1997)). And plaintiff's other cases (Resp. Br. at 3) do not prevent judicial notice of Seprafilm's regulatory status, either. In *Loeb Industries, Inc. v. Sumitomo Corp*., 306 F.3d 469, 479 (7th Cir. 2002), the judge relied in error on testimony and other facts from a class action which were neither in the public record nor undisputed. In *Fleischfresser v. Directors of School Dist. 200,* 15 F.3d 680, 684 (7th Cir. 1994), the materials considered by the court were likewise not part of the public record and disputed by the parties.

Plaintiff has not contested any of the precedent offered by Genzyme (Open. Br. at 4), including the cases where facts in the public record maintained by the FDA were considered in deciding a Rule 12(b)(6) motion to dismiss. Equally important, plaintiff does not dispute – indeed, could not in good faith dispute – the specific fact offered by Genzyme, that Seprafilm is a Class III medical device that received approval from the FDA under the PMA process, or that the regulatory status of Seprafilm is a matter of public record.

In short, under a well-established exception for undisputed facts in the public record, nothing prevents this Court from (a) taking judicial notice of the fact in the public record that Seprafilm is a Class III device approved through the PMA process and (b)

using that fact to rule on the pending motion to dismiss. Taking judicial notice under these circumstances serves the interests of judicial economy and efficiency by avoiding the need for unnecessary proceedings.

II. Plaintiff's Strict Liability, Negligence and Implied Warranty Claims do not Parallel Federal Requirements and are Preempted by the MDA.

Plaintiff mounts two arguments in an effort to overcome the preemption clause of the MDA. On one hand, plaintiff argues that his claims "parallel" the federal requirements imposed on Genzyme and, therefore, fall outside of the reach of the preemption clause. (Resp. Br. at 6-7.) On the other hand, and without appearing overly concerned by the inherent contradiction, plaintiff argues that Genzyme's motion to dismiss should be denied because proposed legislation would amend the preemption clause and allow claims like the ones here to proceed. Neither of these arguments, however, overcomes dismissal.

The notion that plaintiff's common law claims are "parallel" to federal requirements for Seprafilm utterly misconstrues the holding in *Riegel*. Although plaintiff's theory is opaque, he appears to be arguing that his state law tort claims against Seprafilm "parallel" the federal requirements for the device because, like the FDA, his lawsuit seeks to ensure the safety and efficacy of Seprafilm. (Resp. Br. at 7-8.) Plaintiff's concept of parallel claims, however, has no legal basis, and certainly no basis in *Riegel*.

The *Riegel* court held that "a State's 'requirements' include its common-law duties," recognizing that state law actions could impose safety and efficacy requirements that conflict with federal requirements ("a tort judgment . . . establishes that the defendant has violated a state-law obligation"). *Riegel*, 128 S. Ct. at 1008. In the case of a Class III

device approved through the PMA process, the FDA imposes multiple device-specific safety requirements. *Id.* at 1007 ("Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review – it *is* federal safety review."). Thus, state-law claims including strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale which challenge safety and effectiveness – like the claims here – are preempted. *Id*. at 1009-10. An exception is when claims are premised on violations of the federal requirements embodied in the PMA process specific to the challenged device. *Riegel*, 128 S. Ct. at 1011.

Plaintiff's claims do not fall within this exempted category. His highly conclusory pleading asserts no more than general allegations of negligence, strict liability and implied warranty that Seprafilm was not adequately tested or designed in order to ensure its safety and fitness. Noticeably absent are any allegations that Genzyme failed to comply with the FDA's device-specific requirements for Seprafilm. Plaintiff's claims are exactly the sort that *Riegel* held were preempted.

Plaintiff's reliance on *Medtronic v. Lohr*, 518 U.S. 470 (1996) misses the mark. *Lohr* involved a medical device that was approved under the "§ 510(k)" process and was not subjected to the intense scrutiny of the PMA process with its device-specific requirements. *Riegel*, 128 S.Ct. at 1007 ("While devices that enter the market through § 510(k) have 'never been formally reviewed under the MDA for safety or efficacy,' the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness, § 360(d).") (quoting *Lohr*). As the *Riegel* court pointed out, *Lohr* is distinguishable precisely because of the regulatory

differences: the federal manufacturing and labeling requirements under the § 510(k) process apply "across the board to almost all medical devices" and do not preempt the common-law claims of negligence and strict liability. *Id.* at 1006.

Even before *Riegel,* the majority of courts had concluded that the types of tort claims at issue here, against a Class III device that was approved through the PMA process, were preempted. *See, e.g., Mitchell v. Collagen Corp.,* 126 F.3d 902, 913-14 (7th Cir. 1997); *Mattingly v. Medtronic, Inc.*, 486 F.Supp.2d 964, 967 n.3 (E. D. Mo. 2007) (citing decisions from the Second, Third, Fifth, Sixth and Seventh Circuit Courts of Appeal holding that tort claims were preempted). The *Mitchell* decision drives home the point. PMA approval of a Class III device means "approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling." *Mitchell,* 126 F.3d at 913. "A state court judgment premised on a contrary determination, as a finding of liability based on the [plaintiff's] strict liability claim necessarily would constitute . . . a requirement 'different from, or in addition to,' the standard required by federal authority", *id.*, and would "necessarily conflict with a determination of the FDA that its requirements rendered the product safe and effective." *Id.* at 906. As a result, *Mitchell* preempted claims of negligence, strict liability and breach of implied warranty, whether premised on inadequate warnings, design, testing, manufacturing, marketing or sale of the device. *Id.* at 913-15.

Even plaintiff's authority supports preemption. In *Mattingly v. Medtronic, Inc.*, (cited in Resp. Br. at 12 and preempting strict liability, negligence and breach of implied and express warranty claims for all failure to warn, design and manufacturing defects), the court observed that the majority of federal circuit courts had "concluded that (1)

approval through the PMA process, unlike the § 510(k) process, amounts to a federal device-specific requirement, and (2) common law tort actions that allege liability as to a PMA-approved device, notwithstanding that device's compliance with the PMA-approved standards, would conflict with that federal device-specific requirement."[1] *Mattingly*, 486 F.Supp. 2d at 967, n.3.

Plaintiff's argument that his particular claims seek to impose "parallel" requirements, and not ones that are in addition to or different from those mandated by the federal government rings hollow. In this complaint, there is not a single reference to any specific instance in which Genzyme failed to comply with the specific requirements imposed by the PMA order. The complaint fails, even once, to address the device-specific requirements that apply to the challenged product (as opposed to general manufacturing and labeling practices) nor does the complaint even once allege that Genzyme failed to comply with the mandates of the FDA's order granting Seprafilm PMA approval. In fact, the complaint clearly alleges that the Seprafilm used to treat

---

[1] *Mattingly* also cited FDA's explanation for why state law tort actions would impose different or additional requirements:

> State common law tort actions threaten the statutory framework for the regulation of medical devices, particularly with regard to FDA's review and approval of product labeling. State actions are not characterized by centralized expert evaluation of device regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population–the central role of FDA–sometimes on behalf of a single individual or group of individuals. That individualized redetermination of the benefits and risks of a product can result in relief–including the threat of significant damage awards or penalties– that creates pressure on manufacturers to add warnings that FDA has neither approved, nor found to be scientifically required, or withdrawal of FDA-approved products from the market in conflict with the agency's expert determination that such products are safe and effective. This situation can harm the public health by retarding research and development and by encouraging "defensive labeling" by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments.

Mattingly, 486 F. Supp. 2d at 968. Thus, a finding by a state law fact-finder that the device was defective would necessarily impose requirements on the device that are "different from, or in addition to," the requirements of the FDA.

plaintiff's wife reached her without having undergone any substantial changes in its condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned, and otherwise distributed. (Complaint ("C.") ¶32.) Absent any specific allegation that Genzyme failed to comply with the device-specific requirements that were part of the PMA order for Seprafilm, the claims cannot be said to seek "parallel" enforcement of the federal requirements.

Nor does plaintiff's argument about the existence of a regulation that permits a temporary change in advance of a PMA supplement save the claims here. (Resp. Br. at 5, citing 21 C.F.R. §§ 814.39(d)(1) and (2)). In *McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005), the plaintiff offered the same regulation (§ 814.39) in arguing that his claims merely "complemented" the federal requirements for safety and efficacy. *Id*. at 489-90. The court reminded plaintiff that "[w]here a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." *Id.* *McMullen* held that § 814.39 did not impose a "genuinely equivalent" duty to the requirements that might arise under state common-law. *Id.* In any event, the regulation clearly retains for the FDA the power of review and approval of any such change, bringing it squarely within the PMA process and thus within the scope of the express preemption clause.

Similarly, speculative remarks concerning a failure "to inform the FDA of scientific studies or incidents of death or injuries" (Resp. Br. at 5-6) are not enough to save plaintiff's claims. Certainly nowhere is this issue raised in plaintiff's complaint. In fact, the complaint expressly indicates that the FDA has received evidence of "injuries, including death, for those persons who have endured a surgical procedure and were given

Seprafilm" (C. ¶13) and that the FDA is aware that Seprafilm has been connected with cases in which some patients developed concrete intestines, (C. ¶14). There is no claim that Genzyme failed to comply with its FDA reporting obligations and plaintiff's remark on this point is both irrelevant and misleading.

Plaintiff apparently understands that his position with respect to the strict liability, negligence and breach of implied warranty claims is doomed. That must be why he attempts to forestall the inevitable by pointing to proposed legislation being discussed by some members of the U.S. House of Representatives to override *Riegel.* (Resp. Br. at 8.) Ironically, the fact of proposed legislation reinforces defendant's point, that *Riegel* requires dismissal of claims like the ones alleged here. As plaintiff's own citation states (Resp. Br. at 8, article cited in note 3), the draft bill seeks to amend the MDA because "the Supreme Court's Feb. 20 decision in *Riegel v. Medtronic* 'denies patients any legal recourse if they are a victim of a faulty medical device'. . . ."

Waiting until some unspecified future time for legislation possibly to emerge that may or may not override a U.S. Supreme Court decision serves no meaningful purpose. *See, e.g., EEOC v. Bethlehem Steel Corp.,* 727 F.Supp. 952, 955 (E.D. Pa. 1990) ("Would not the concept of finality in the American system of justice be rendered meaningless if we are going to delay entering judgment because of future actions that a legislative body might take?"); *Gabarczyk v. Bd. of Ed. of the City School Dist. of Poughkeepsie,* 738 F.Supp. 118, 121 (S.D.N.Y. 1990) (accord); *Warren v. Oil, Chemical and Atomic Workers Union-Industry Pension Fund,* 729 F.Supp. 563, 570 (E.D. Mich. 1989) (accord). It is anyone's guess whether the proposed bill will gain traction in the House, approval in the Senate, would be veto-proof or apply retroactively to claims filed prior to

its hypothetical passage. In short, there is no sound reason to defer a ruling on this motion to dismiss and the motion should be granted under current law.

III. Plaintiff's Negligence Per Se Claim Fails Because the Complaint Omits Essential Required Elements and Plaintiff's Proposed Amendments Cannot Cure the Deficiency.

Plaintiff argues that he satisfied the requirement to set forth a relevant standard of care for purposes of his negligence *per se* claim simply by referencing the Federal Food, Drug and Cosmetic Act and the MDA. (Resp. Br. at 9-10) Plaintiff is wrong. As a matter of law, a vague reference to an overarching piece of legislation is insufficient to establish the existence of a relevant standard of care with respect to the specific challenged device. *See, e.g., Talley v. Danek Medical Inc.*, 179 F.3d 154, 160-61 (4th Cir. 1999) (rejecting plaintiff's argument that any violation of the FDCA was sufficient to establish breach of a relevant statutory standard of care and holding that "not all statutory provisions dictate a standard of care, and therefore not all statutory violations can provide a basis for establishing negligence *per se*").

Plaintiff impliedly concedes this point by offering to amend his complaint "to include the more specific medical device warnings codified at 21 C.F.R. [§§] 801.1 [and] 801.6." (Resp. Br. at 10) But his proposed amendment would not cure the complaint's defects because the cited regulations are rules of general applicability that do not impose device-specific requirements under the PMA process. Section 801.1 ("General Labeling Provisions") merely sets forth the obligation that all medical devices should be labeled in a manner that identifies the name and place of business of the manufacturer, packer or distributor. The other general provision offered by plaintiff, § 801.6, prohibits a manufacturer from including a false or misleading representation with respect to "another device" in the labeling of its own devices. Because these general regulations are not

device-specific and say nothing about the labeling requirements imposed on Seprafilm through the PMA process, they do not represent a relevant standard of care. Moreover, even if the amendments were allowed, plaintiff's complaint would still lack the specific allegations necessary to establish that Genzyme breached §§ 801.1 and 801.6 or allegations to establish proximate causation.

The specific requirements for the standard of care required of Genzyme's Seprafilm are embodied in its PMA order. *See Riegel*, 128 S. Ct. at 1007 ("premarket approval is specific to individual devices" and "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application"). Absent any specific reference to requirements from the PMA process or conduct by the defendant that breached these substantive requirements, plaintiff's negligence *per se* count – even if amended to incorporate a reference to 21 C.F.R. §§ 801.1 and 801.6 – remains defective and should be dismissed.

Finally, plaintiff's vague reference to a purported "failure to adhere to the PMA mandated requirements regulating Seprafilm," (Resp. Br. at 12) does nothing to warrant a different conclusion: there is no allegation about the nature of the failure, much less how these requirements were violated.

IV. Plaintiff's Breach of Express Warranty Claim Is Preempted.

Plaintiff argues that his express warranty claim is predicated on "statements made by Genzyme or their authorized agents, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Seprafilm was safe, effective, fit and proper for its intended use." (Resp. Br. at 13, *quoting* C. ¶49). He claims that this warranty was breached because "Seprafilm was not

safe and was unfit for the uses for which it was intended." (C. ¶50). Those are exactly the type of cursory allegations, however, that fail to prevent dismissal because the allegations do nothing more than replicate the PMA requirement for a device to be safe and effective – allegations that are preempted. Plaintiff's own case makes that very point:

> [T]he PMA process of the device requires an actual finding by the FDA that the device is both safe and effective. See 21 C.F.R. § 814.2(a). Thus, Plaintiffs contention that Defendant represented that the device was "safe and effective" and that it was not because of the alleged defect necessarily is seeking to impose requirements that are "different from or in addition to" those required by the FDA under the PMA process . . . .

Mattingly v. Medtronic, Inc., 486 F. Supp. 2d 964, 968 (E. D. Mo. 2007) (cited in Resp. Br. at 12).

Similarly, plaintiff misconstrues the holding in *Richman v. W.L. Gore & Assocs., Inc.*, 881 F. Supp. 895, 905 (S.D.N.Y. 1995) (cited by plaintiff in Resp. Br. at 13). The *Richman* court did not hold that express warranty claims are beyond the reach of the preemption clause. Instead, it granted a Rule 12(b)(6) dismissal of the express warranty claim against a medical device because it was inadequately pleaded. Just as in *Richman*, the complaint here "states only a conclusory legal claim with respect to the breach of express warranty. Such a claim is not well-pleaded and cannot withstand a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure." *Id.*

Moreover, a manufacturer of a PMA device is required to conform with the FDA's requirements for the product's safety and effectiveness. Consequently, an alleged warranty that the product is safe and effective "does not result from a contractual commitment 'voluntarily' undertaken" and, therefore, is preempted. *Rattay v. Medtronic, Inc.*, 482 F. Supp. 2d at 746, 762-63 (N.D. W. Va. 2007) (*citing Duvall v. Bristol-Myers-*

Squibb Co., 103 F.3d 324 (4th Cir. 1996)). *See also Gomez v. St. Jude Medical Daig Div., Inc.*, 442 F.3d 919, 932 (5th Cir. 2006) (holding that because a device maker's representations about a device "were approved by the FDA through the PMA process," and because the duties underlying the breach of express warranty claim were potentially inconsistent with federal regulations, the claim was preempted).

Here, plaintiff has put forward a conclusory claim that Genzyme should be held liable for warranting the safety and effectiveness of a Class III device that was approved through the PMA process. This claim, in addition to being inadequately pleaded (Open. Br. at 9), must be dismissed under the preemption clause.

V. Plaintiff Offers Nothing to Sustain the Statutory Claims (Counts I and II).

Plaintiff has abandoned Count II for deceptive marketing (Resp. Br. at 14-15) and Genzyme agrees that Count II of the Complaint should be dismissed for the reasons set forth in its Opening Brief. As for Count I, for breach of implied warranty, Plaintiff fails to challenge the authority cited in defendant's opening brief. *(See* Open. Br. at 6-7, *citing Mendes v. Medtronic, Inc*., 18 F.3d 13, 19 (1st Cir. 1994)). *Mendes* shows that the plaintiff's implied warranty claim, pleaded under Mass. Gen. L. ch. 106, § 2-314, is preempted because it is "congruent, in all material respects" with a strict liability claim and a defendant" could be found liable even if it meticulously followed FDA's good manufacturing practices." *Id.* Therefore, the statutory counts should be dismissed.

VI. Plaintiff Concedes that Genzyme Had No Direct Duty to Warn Him and Therefore the Duty to Warn Claims as Plead Must be Dismissed.

Plaintiff cannot get around the fact that the learned intermediary doctrine is the law of Illinois in failure-to-warn tort actions against a prescription product like Seprafilm. Instead of conceding that his complaint lacks the necessary warning allegations, the

plaintiff offers *Hansen v. Baxter Healthcare Corp.*, 198 Ill. 2d 420 (2002) (Resp. Br. at 14), which was first cited by Genzyme in its opening brief. The *Hansen* decision entirely supports Genzyme's position here, reiterating that

> the manufacturer of a prescription medical device has a duty to warn prescribing physicians or other health professionals who may prescribe the device of the product's known dangerous propensities. Likewise, physicians, using their medical judgment, have a duty to convey the warnings to their patients. The duty to warn the health-care professional, rather than the ultimate consumer or patient, is an expression of the "learned intermediary" doctrine.

Id. at 431 (citations omitted).

The complaint here fails to allege any failure on Genzyme's part to warn the medical community. Nor can plaintiff cure the lapse by arguing, as he does in his response brief, that what he really meant to say is that Genzyme failed to warn the plaintiff "through" the learned intermediary. (Resp. Br. at 14.) Whether or not the *plaintiff* was warned by Genzyme about the risks of use is simply not an element of a claim against the company.

In any event, failure to warn claims that would impose requirements other than those mandated by the FDA are preempted. *Riegel*, 128 S. Ct. at 1011. *See also O'Neal v. SmithKline Beecham Corp.* 2008 WL 1721891, *6 (E.D. Cal. 2008) (preempting all failure to warn claims because each is "encompassed within" *Riegel*). As a matter of law, the plaintiff has not pleaded the elements of a failure to warn claim and all such claims should, therefore, be dismissed.

CONCLUSION

Wherefore, for the reasons set forth in Genzyme's opening brief and this reply brief, all counts of the complaint should be dismissed.

Respectfully submitted,

Genzyme Corporation

By: /s/ Stephanie A. Scharf
Stephanie A. Scharf – Atty. No. 06191616
David W. Austin – Atty. No.: 6273729
Schoeman Updike Kaufman & Scharf
333 W. Wacker Dr., Suite 300
Chicago, IL 60606
Telephone: (312) 726-6000
Facsimile: (312) 726-6045